U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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FRAMEWORK FOR PHARMACY COMPOUNDING: STATE AND FEDERAL ROLES

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WEDNESDAY
DECEMBER 19, 2012

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The Meeting convened at the FDA White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, Maryland, at 3:00 p.m., Margaret Hamburg, Commissioner, and Heidi Marchand, Moderator, presiding.

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PRESENT

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HEIDI MARCHAND, Moderator
JANE AXELRAD, Food and Drug Administration
PETER BECKERMAN, Food and Drug Administration
ILISA BERNSTEIN, Food and Drug Administration
BERNADETTE DUNHAM, Food and Drug Administration
ELLEN MORRISON, Food and Drug Administration
HOWARD SKLAMBERG, Food and Drug Administration
JOHN KIRTLEY, Southwest Region
JAY CAMPBELL, Southeast Region
CODY WIBERG, Central Region I
ASA YI, Central Region II
LAWRENCE MOKHIBER, Northeast Region
MARK JOHNSTON, Pacific Region

P-R-O-C-E-E-D-I-N-G-S

MODERATOR MARCHAND: We have about 500 on the webcast, as well. So, welcome to FDA, good afternoon.

My name is Heidi Marchand, and I direct the Office of Special Health Issues here at FDA, and I'll be your moderator for this afternoon.

As you're settling in please remember to turn your cell phones off or put them on the silent mode. And I will be pleased to introduce to you our Commissioner, our 21st Commissioner, Dr. Margaret Hamburg.

She's been the Commissioner since May of 2009. She's a physician and graduated from Harvard Medical School. She's held the position of Commissioner with the New York City Department of Health and Mental Hygiene, and has held academic appointments at Columbia School of Public Health and at Cornell Medical College.

In 2001, Dr. Hamburg became Vice

President at the Nuclear Threat Initiative, and its senior scientist. While there she advocated broad reforms in public health and policy to mitigate the dangers of bioterrorism threats, as well as naturally occurring threats like pandemic flu. Without further delay, Commissioner Hamburg.

COMMISSIONER HAMBURG: Well, thank you very much, and I want to welcome all of you who are just joining us now for this public portion of this meeting. And we really are just so pleased that this meeting has been able to happen. We're delighted to have members of the public with us as we move into the final stages of today's very rich discussion. And I also want to acknowledge the people who can't be with us today but are participating on the internet because I do think that having that broader reach is very important.

This is a historic meeting, and hopefully one that will make a real and

enduring difference, but we also realize that it's just a beginning, a critical and essential step in a process of deepening understanding of the issues raised by compounding pharmacies, identification of critical needs and gaps, and delineation of opportunities to move forward together in a more coordinated, comprehensive, and effective way.

This afternoon FDA and representatives from the states will be sharing results from today's intergovernmental meeting talking about the discussions that we've had, and we really this morning had an opportunity for some very full and frank discussions about FDA's relationship with the states and overseeing the pharmacy compounding industry.

We are indeed fortunate that representatives from all 50 states and the District of Columbia, more than 100 people in all, were able to join us for those

discussions. They agreed to travel here on very short notice to take part in this meeting, and they were joined in their discussions by FDA staff, officials here from headquarters, but also our regional FDA representatives, and I think everyone really has benefitted today's discussions. And I think it has strengthened ongoing relationships as well as, of course, enriching our dialogue.

I also have to note that such an impressive turnout on such short notice and in the week before Christmas holidays, you know, really speaks to the gravity and the urgency of this set of concerns, and the need we all feel to really work together to better protect the public health through stronger oversight of pharmacy compounding, and to make sure that going forward we are doing the very best that can be done.

As you all know, a little more than two months ago we learned about the

first death from fungal meningitis associated with the steroidal injection methylprednisolone acetate that had been produced by the New England Compounding Center.

As events unfolded, I think we have all been stunned and horrified by the magnitude of the devastation. The stark reality is that 39 people have died with some 620 cases, and thousands of patients have endured months of worry knowing that they'd been injected with implicated lots of this product.

I also want to recognize and express thanks to the many state officials assembled here and their organizations who did such amazing work responding to the emerging outbreak, participating in the investigations, and in reaching out to health care providers, patients, and the public to keep them informed and to help them respond.

Needless to say, caring for this

many patients has also taken a toll on health care systems in the 19 states with reported cases, and has had very significant ramifications that have extended far beyond the borders of those states.

I can assure you that those patients, families, and health care professionals who have labored so hard to address this devastating outbreak have been very much in our thoughts as we have talked today.

Clearly it's imperative that we close the gaps in oversight at the fast-growing compounding industry. The fungal meningitis outbreak is the most tragic, but not the only example of why we must act now. The magnitude of this issue reminds us, though, that FDA cannot and should not be largely reactive in our role of regulating compounding pharmacies. To fulfill our mission we must be able to help support quality practices and products, to

proactively identify dangerous practices before they result in actual harm, and when necessary intervene to minimize the damage and to prevent future similar events.

The need to be proactive on compounding, of course, underlies part of why we so wanted to undertake this 50-state meeting today. FDA believes that we all have a shared public health mission, and it is this mission that must drive our approach and will be the most effective approach for the oversight of pharmacy compounding that includes medications for both humans and for animals.

As I discussed with the group earlier this morning, I do want to emphasize that the states play a fundamental role in the oversight of traditional compounding and they should continue to do so. By traditional compounding I mean licensed pharmacists engaged in the combining or altering of ingredients in response to a licensed

practitioner's prescription for an individual patient to produce some medication tailored to that patient's needs.

Traditional compounding provides a valuable service to the health care system, and this practice should remain subject to the state regulation of the practice of pharmacy. But some compounding pharmacies have evolved beyond small-scale community operations. As these facilities have moved to large volume production, to shipping across state lines, to producing sterile products from non-sterile ingredients, the risk to patients have increased.

FDA has seen an increasing number of incidents related to drugs from some of these pharmacies with NECC as the latest and, of course, the most certain incident to date. But consider some of these earlier examples. In 2005, gram-negative rods, a type of bacteria that can cause disease and infection were identified in two lots of cardioplegia

solution made by a firm in Maryland. These were reports of five cases of adverse events, including three deaths associated with this contaminated cardioplegia solution.

In 2007, a cluster of infections occurred after patients received infusions of fentanyl made by a firm in Mississippi. One patient died of acute respiratory distress and multi organ failure.

In 2009, FDA received reports of nine patients who contracted orbital cellulitis, a type of eye inflammation following administration of a compounded injectable product made by a compounding pharmacy in Florida. At least one of these patients suffered vision loss.

FDA in each of these cases responded to address the underlying problem, but recognized that we needed to be able to do more. We have tried in the past to clarify our position on the oversight of compounding pharmacies by issuing a compliance policy

guide back in 1992 to delineate the agency's enforcement policy on compounding. And when that proved unpopular with industry in 1997, Congress enacted compounding legislation as part of the Food and Drug Administration Modernization Act. This legislation is what added Section 503(a) to the Federal Food Drug & Cosmetic Act.

Section 503(a) exempts compounded drugs from three requirements of the FDCA, premarket approval, compliance with current good manufacturing practice, and requirement that a drug bear adequate instructions for use provided that certain conditions are met. The law does not set an absolute limit on volume as a distinguishing factor between compounding and other manufacturing, nor does the section strictly prohibit anticipatory compounding, or the compounding of drugs that are essentially copies of FDA-approved drugs.

In addition, over the last decade Section 503(a) has been the subject of court

challenges with conflicting opinions amplifying the perceived gaps and ambiguity associated with the FDA's authority of compounding that we confront today. I believe it's time to end the ambiguity and to close those gaps.

During my recent House and Senate Committee testimony, I spoke to FDA's current thinking about the need for a risk-based regulatory system that would create a three-tiered framework, traditional compounding, non-traditional compounding, and manufacturing. Clearly, we've been discussing some of that today, and it's an area where I think we will likely want to have continuing discussions. But in this framework that we're proposing traditional compounding would remain subject to the state regulation of the practice of pharmacy. Non-traditional compounding, and it could be called by many names, would include drugs for which there is a medical need but that pose higher risks

based on factors that might include making sterile products, the amount of product being made, whether the compounded drug is being shipped interstate, or whether the drug is being dispensed to someone other than the ultimate user once it leaves the facility where it was produced.

Non-traditional compounding would be subject to federal safety and quality standards adequate to insure that the compounding could be performed without putting patients at undue risk. And we could partner with states who are willing to take on responsibility of overseeing non-traditional compounding activities within their states, and if they can demonstrate their ability to protect the citizens of other states through effective oversight.

Certain types of products, because of the higher risk they present, could not be compounded at all in the schema, and these could only be made by facilities

willing and able to adhere to the full range of controls and practices required of drug manufacturers.

We believe that this three-tiered approach would appropriately balance legitimate compounding that meets a genuine medical need with the reality that compounded drugs pose greater risks than products that are evaluated by FDA for safety and efficacy, and subject to manufacturing control to insure consistently high quality.

Since the outbreak, FDA has engaged a variety of stakeholders, pharmacy groups, patient consumer groups, hospital associations and health care networks, professional groups and specialty societies to get their views about pharmacy compounding. We've spoken with over 50 different organizations and have heard a wide spectrum of views on this matter.

Today it was the states' turn, and I think that we've been doing a pretty

deep dive. Representatives from the offices of the governors, State Departments of Health and the State Boards of Pharmacy came together this morning and then split up into breakout sessions, as I mentioned, to provide more background on the nature and role of compounding pharmacies in their various states, how these pharmacies are regulated, and to discuss four questions that get to the heart of the federal and state role.

Many of us at the FDA had a chance to circulate from room to room to listen in on these discussions, and I think everyone was impressed with the level of energy and engagement. Important issues were raised that we certainly need to address.

We heard some things that I think we can act on quickly, and we heard some things that are more complex, will require more discussion, and certainly underscore the important role that new legislation can play. But, for example, one of the things that we

heard consistently and clearly is the need for greater communication, back and forth communication, more openness, transparency. And I think that we really have a lot of opportunity to address that starting today and the need to work on a local, regional, and national basis as we engage and work to address our day to day challenges, and to make sure that we have systems in place to prevent the kind of tragedy of the recent meningitis outbreak.

We recognize that today's crowded agenda did not leave us time for a more open public meeting and a chance to hear from the public, but I do want to emphasize that we are eager for input from any and all who want to share their perspectives, experiences, and ideas on this critical issues of pharmacy compounding practice, so we urge you to submit your written comments to us. We have opened a formal docket, and that will be closing on January 18th.

Today's intergovernmental meeting was not about achieving consensus. We don't expect that we will leave here today with absolute answers and final solutions, but rather our goal was to really deepen our understandings of the issues before us, and about the beginning of a new committed partnership to chart a path forward.

What we wanted and I think got was a robust discussion on options for better safeguarding the health of the American people, a discussion that was really focused on learning from experience but looking forward with a goal of how best to close the gaps in the current system, and how best to serve the people of this nation.

Protecting Americans from unsafe and contaminated drugs is not just an important responsibility of the FDA, it goes to our very most central and core mission. And to best fulfill that mission we must have proactive systems in place to identify when

there are inappropriate practices that may put products and people at risk. We must have the tools to act before they result in actual harm, and when necessary to intervene to limit damage and prevent future problems.

Compounding pharmacies have presented particular challenges but we can and must address them. And we must do it together. Certainly for us at the FDA, we recognize that we can do the most effective work when we do it in partnership. This is a shared responsibility. The states are obviously in the front lines of so much of this activity, and the opportunity to really strengthen, deepen, and extend our working relationship to clarify important issues that matter to our ability to serve the American people, and to work together to really identify what more needs to be done as we pursue this critical goal of creating a comprehensive, integrated, and strong safety net that will assure and support quality of

the products that the American people rely on and trust.

So, thank you very much. Let's get to the next part of our session.

MODERATOR MARCHAND: Thank you very much, Dr. Hamburg. I know it's been a very active day for the states' representatives. They've been exchanging ideas and have had a lot of discussion specifically focusing on the four questions that we put forward in the Federal Register Notice announcing the public meeting, so, we're very interested in hearing the comments. But before we begin, I'd like to introduce our FDA listening panel.

To the left of Dr. Hamburg is Bernadette Dunham who's the Director for the Center for Veterinary Medicine. To her left, Ellen Morrison who is the acting Assistant Commissioner for Field Operations in the Office of Regulatory Affairs. To her left is Howard Sklamberg, who's the Deputy Associate

Commissioner for Regulatory Affairs. To his left, Peter Beckerman, the Senior Policy Advisory in the Office of Policy in the Office of the Commissioner, followed by Jane Axelrad, the Associate Director for Policy and Director for the Office of Regulatory Policy, Center for Drug Evaluation and Research. And Ilisa Bernstein who's the Acting Director for the Office of Compliance in the Center for Drug Evaluation and Research. So, let's begin to hear our working groups.

If we can, James can switch to our slide that shows our Discussion Topic 1, that is given the existing authorities and resources are states currently able to provide the needed oversight for pharmacy compounding and consumer protection? And we'll begin to hear from three different regions. Each of the individuals are representing their individual state, but as we worked in working groups by region and in

order to hear from a broad range of different perspectives we'll have in response to this discussion topic three regions giving an overall summary to this topic. And with that, I'd like to start with the Southwest Region, John Kirtley from Arkansas.

DR. KIRTLEY: Thank you. My name is John Clay Kirtley. I'm the Executive Director of the Arkansas State Board of Pharmacy. I just want to start out by thanking Dr. Hamburg and for our colleagues at FDA for having us all here today. I think it's quite a feat to get 50 states in this area all at once a week before Christmas, and I think we've had a lot of good interaction.

Just tying into this question for the Southwest region specifically, we've already highlighted the fact that this is not necessarily consensus document for all of us, but it indicates a lot of points. I think the first thing that we would like to recognize is that we're all here due to in large part

drug shortages and the need for outsourcing and finding alternative means to treat out patients. It's something that when our boards discussed it, we all are struggling with some clarity on definitions. We hear a lot of terms that are used by different people as professional jargon, whether it's traditional compounding, non-traditional compounding, manufacturing, outsourcing. We have all these definitions, and I think we really do need to work towards consensus statements, potentially even from the federal authorities of what exactly the terms mean, and how they are defined so we all know how to interpret them.

The next thing is we're asked if we're comfortable with what's happening, and if we can handle oversight of this. And I think that the states in the Southwest region were very comfortable with what may be going on in our own states, but then you have a point of concern. We know what happens in

pharmacies in Arkansas. We don't necessarily know about what is happening to specific pharmacies in other states that ship into our state. So, when we look at that compounding, when you define it as a patient-specific prescription, we have the resources, we have the ability to go in and look at all of pharmacies, and all of the states in this region believe so.

Where it gets sticky and where there's a little bit of discord is when you get beyond that definition, when prescriptions that are compounded cross state lines, first of all, or when they're -- you have anticipatory compounding of some sort that is outsourced to another facility and crosses state lines, and there's some discussion that there may be some more oversight for that type of setup.

Some believe that in our own states whatever the compounding is, whether it's for a specific patient, whether it's

outsourcing for a hospital prescriber, office doc, we're completely comfortable because, once again, it's our state, it's our oversight and we're in those pharmacies.

However, there's been some discussion that large volumes that are not produced pursuant to prescriptions that cross state lines, that there ought to be FDA oversight on that and we recognize it.

Other types of compounding is a concern. During this meeting and most of the focus on this whole topic has been about pharmacies and pharmacists, and whether it is a traditional or non-traditional practice, or manufacturing. You know, there's a whole other arm of this when we start talking about compounding in prescriber offices, prescribing in clinics, or how compounding happens in hospitals, so when we're talking about regulatory oversight and people meeting specific criteria, those criteria are defined fairly well by a lot of states. They are

defined very well by what volume you're doing, or whether it crosses state lines or not.

For us, we would require sterility, pyrogen, and potency testing for certain batch sizes, but in some facilities if you stay and you just do something for immediate use or for fairly quick use for a specific patient it may not have the same scrutiny.

This region, the Southwest, feels it can provide oversight of pharmacy compounding because we have on the ground knowledge and the resources to provide these services. We have many times autonomous boards where we have our own funding source from the licensees, we have our own staff that we don't share with other people, and we don't have to, and we can do our own investigation and our own inspection activities. With this, we have responsibility and oversight authority on both the business

side and on the individuals, so if there's a bad actor business we can take action on the business. If there's a bad actor pharmacist or pharmacy staff person, we often have the ability to take action on them, as well.

With this, we also often have the strength in having professional staff that are pharmacists with years of experience and additional training in these specific areas, and that's something that gives us a good bit of comfort. So, I think that wraps up the Southwest region. I'll try to not be repetitive and give these guys some answers, as well.

MR. CAMPBELL: Hi, I'm Jay Campbell, the Executive Director of the North Carolina Board of Pharmacy, and I'm going to address the same issues John did coming at it from the perspective of those states that were -- we were grouped together for the Southeast. I echo with John that these questions aren't necessarily amendable to

consensus answers from all the states, but we have attempted to coalesce the responses into their principal themes.

To try to pick up a little bit and not be unduly repetitive of what John said, one of the questions I think you have to ask, and all states do ask with respect to the ability to regulate pharmacy practice within their states, whether it's compounding, or whether it's not compounding, is the structure of the Board of Pharmacy and the resources available to the Board of Pharmacy; are they sufficient to do that?

The feeling among Southeastern states was that the answer to that is generally yes. John pointed out that structurally Boards of Pharmacies differ from state to state, and some states, as in North Carolina, we are largely an independent agency with our own independent funding source, and our own independent ability to hire or dismiss, as the case may be,

inspectors and investigators. And we are adequately staffed to have a constant source in the field, on the ground, in the pharmacies enforcing standards and proactively identifying potential problem pharmacies. And states within the Southeast felt like that by and large they have the resources to do that; although, some did point out that state governments generally in this country are dealing with revenue challenges, and vigilance on the part of State Boards of Pharmacy is important to maintain those sufficient resources, as is perhaps more importantly a recognition by state legislatures that Boards of Pharmacy must be adequately funded and resourced to protect the public health and safety and not simply be viewed as a vehicle for providing a revenue stream to a general fund. Again, in the Southeast our feeling was that our state governments by and large recognize the public health mission of the boards and have

structured and funded us to handle those missions.

I share with John is that I think we all classically think we feel great about what we do in our state, but gosh, we don't know what those other guys are doing. And that is a challenge. Sometimes it's well founded, sometimes it's not well founded, and some of the issues we discussed in terms of operating among the states, so that's -- I'm addressing interstate, not between the states and the federal government.

I think there was a feeling that states can and should do a better job of at least establishing relatively uniform minimum standards for compounding and, in particular, sterile compounding. USP 795 and 797 standards are the ones most commonly bandied about, and those -- and in addition to thinking that there perhaps ought to be minimum standards that are relatively uniform, that there also be adequate training

available to state investigators that provide what all states would deem as a comfortable, healthy level of confidence and experience so that, for example, in North Carolina if I have a pharmacy licensed in Arkansas, I'm very comfortable as I am, I'm very comfortable knowing that their standards and the quality of their investigators and inspectors are such that I can take comfort when they seek a permit in North Carolina.

The other thing we discussed is that the states -- we need to continue to work on our ability to share information among each other on either pharmacies or pharmacists that have proven to be problem pharmacies or pharmacists, or pharmacies or pharmacists that we think are trending toward being a problem and taking appropriate proactive measures.

With respect to pharmacists around the United States, there are very good existing database sharing mechanisms which my

board any other Board of Pharmacy any time an individual pharmacists seeks licensure in our states, we can tap into a database administered by the National Association of Boards of Pharmacy and get a complete disciplinary history on that pharmacist, so we know what it is we're getting, and whether there are red flags that we need to be aware of.

With respect to pharmacies, those same sorts of databases as of this date are not -- don't exist. And I think we all agree that we would like to, and I can report that through the National Association of Boards of Pharmacies we are now implementing a similar system such that if a pharmacy in Cody's State of Minnesota is applying for an out-of-state permit in North Carolina, we have a ready source to identify for us any disciplinary action that's been taken by any other State Board of Pharmacy, or against that pharmacy or its affiliated pharmacists,

and let that guide our decision making.

I will discuss the note with the next Topic 3, that when it comes to us, how we'd like to see some of that same information or actually all of that same information sharing coming from the FDA into a similar system.

So, we have things among the states that we can improve in terms of information sharing and some standardization of requirements, and I feel quite good that those processes either are in place or they're in process.

DR. WIBERG: And I'm Cody Wiberg, the Executive Director of the Minnesota Board of Pharmacy. And first, I'd also like to thank the FDA for hosting these meetings today. I think it's very critical for the federal and state governments to work very closely on this very difficult issue, an issue that is quite a bit more difficult to address than some might imagine because

there's really a number of sub-issues, if you will, that are interlocked, and taking actions in one area may have an adverse effect in what happens in these other areas.

Now, this first discussion topic talks about whether or not given existing authorities and resources the states currently can provide needed oversight of pharmacy compounding. And I think that's one of the first things that you need to discuss, is what's the definition of pharmacy compounding. And many of the discussions that we had in the regional group I participated in today really centered around those issues of definition.

What is the definition of compounding? What is the definition of manufacturing? Should -- what facilities like the New England Compounding Center, should the activities they were engaged in be classified as non-traditional compounding, or non-traditional manufacturing? And you'll

find that the states have differing laws and rules that regulate the practices of compounding and manufacturing.

I think that in most of the states in the region that I was in, compounding is something that's done pursuant to a prescription for an individual patient. Just about anything else is manufacturing. It doesn't necessarily mean that the manufacturing processes that are used under the definition we use for manufacturing are necessarily wrong. There is a need for a -- what in our state would be a non-traditional manufacturing process to provide for certain drugs in certain situations.

So, I guess, however, when our group looked at this question we were looking at it in terms of do the states have the ability right now to provide oversight, if you considered what an entity like NECC was doing to actually be compounding. And I think the answer to that question is it depends on

the state.

There are some states that do have the necessary authority to act when they need to, and they have the necessary resources. Although, I will say that in most states, as Jay mentioned, over the last decade there's been a constant budget issue, and there's been a constant fight to maintain our resources, to maintain our staffing, to maintain our appropriations, but there are some states that do have the necessary authority, and the resources to provide adequate oversight not of just what we would call traditional compounding in Minnesota, but also the sort of activities that NECC was doing that we would call manufacturing. But there are other states that probably don't.

One of the things that is mentioned that we talk about at the District and National meetings of the National Association of Board of Pharmacy is how some states don't really always have the resources

that they need to regulate the practice of pharmacy.

Some states have, like Minnesota, have inspectors who are licensed pharmacists, who have training and expertise in compounding. Other states don't do routine inspections at all, but only inspect pharmacies as a result of complaint investigations. Their inspectors may not actually be pharmacists, they may have to actually contract with someone else to do their complaint investigations, or get a pharmacist involved in their complaint investigations.

In some states, the Board of Pharmacy will regulate not only pharmacies but manufacturers and wholesalers. In other states, the Board of Pharmacy might regulate pharmacies but a different agency might regulate manufacturers.

When you're talking about the sort of activities that NECC was involved in,

it becomes crucial who regulates pharmacy versus who regulates manufacturers because that sort of activity has features of compounding, and it has features of manufacturing.

And I think to echo from my colleagues who've talked about it here, is just about every state, not all of them I found out today, I was surprised, but almost all states regulate non-residential or out-of-state pharmacies, license them. So, if a pharmacy or actually a manufacturer or a wholesaler wants to ship any sort of drug product in Minnesota, into Minnesota they need to be licensed by the Minnesota Board of Pharmacy. And up until now, we pretty much depended on the other states to regulate them, the states in which they're located. So, that is a potential issue; is if, in fact, there are states that don't have sufficient funding, don't have the resources necessary to regulate facilities in their

state, that can have an impact on every state that licenses their facilities.

So, the answer to this question I think is -- again, it really depends on what you're talking about. I think if you're talking about traditional compounding pursuant to a prescription that's done in -- actually in Minnesota at least, in just about every pharmacy does some degree of traditional compounding, I think most states definitely have the authority and resources to handle that. If you're talking about these non-traditional compounding or non-traditional manufacturing activities in facilities like NECC, fewer states may have the resources to do that. And I do think, and I think the consensus in our group was in the latter case in facilities like NECC, there is a role for the FDA to be involved.

MODERATOR MARCHAND: Thank you. We'll now open it to questions or points of clarification for the FDA panel. Bernadette.

DR. DUNHAM: Yes, thank you very much. And, again, I want to thank Dr. Hamburg and everybody for participating. This has been an incredible event, and the contribution by everybody is really appreciated and needed.

Just a follow-up for veterinary medicine, it's true many times the pharmacists are, in fact, compounding for both animal or human. And I was just curious as you just mentioned a minute ago the differences that exist between the states. Is this something that there is a lot of difference between pharmacists handling compounding for veterinary products versus human? Because we have had some situations where, in fact, a compounding pharmacy has made both, and both have had problems, which then is very critical. Thank you.

DR. WIBERG: I can probably answer that, and my colleagues might want to chime in, as well.

There is different -- there are differences between states. So, for example, in Minnesota in terms of our statues and rules, compounding is something that's one pursuant a prescription for an individual patient, and it's done in a patient practitioner pharmacist triad. I guess it's a quadrangle when we're talking about veterinary medicine because now we have patients and clients, and veterinarians, and pharmacists. But in Minnesota, there would be no compounding for office use. It's not allowed. However, in other states it is. There are states that will allow, for example, perhaps up to 5 percent of the compounding that's done in the pharmacy to be for office use.

Now, when I talk about this it's, again, recognizing our definitions in our state statutes that distinguish between compounding and manufacturing. It's not that the pharmacy can't necessarily prepare a

product that's going to be end up being used in the office of a veterinarian, but we would require them to be licensed with us as a manufacturer if they're located in the state. And if they're located in another state we'd require them to be licensed by that state as the manufacturer. And if in any situation where we think someone may need to be registered by the FDA, we will say you need to be registered with the FDA or you need to produce a letter from the FDA that tells us why you don't need to be registered. So, it can be done in Minnesota but it's not going to be done under a pharmacy license because a pharmacy license in Minnesota is only going to allow you to compound patient-specific. But, again, and any of the other states can talk about this that may do things differently, in other states a pharmacy, based just on its pharmacy license can compound for office use without having a prescription for a specific patient.

MODERATOR MARCHAND: And could I just remind folks to speak into their microphones and speak loudly?

DR. KIRTLEY: John Kirtley once again. I'm usually known for being loud, unfortunately.

It's interesting because we didn't discuss this necessarily with our region, but for the State of Arkansas, we have often made the point that if you have a quality standard to produce a human drug, we do not differentiate that you have any less of a standard to create a drug for an animal. So, if you are getting something that is compounded for your horse, your dog, your cows, whatever it is, you know, we expect it to reach the same quality standard as if you were giving it for yourself, your grandmother, your child. So, we feel fairly strongly about that, and we do not expect anyone to cut corners. It's something that we routinely inspect on. And, once again, we go

back to this issue of sterility, pyrogen, and potency testing. I don't want your animal getting something that hasn't been proven to be sterile, pyrogen-free, and hasn't been tested for potency if they're batch producing it, so we have that.

MR. CAMPBELL: Back to what John said with respect to North Carolina, there is no difference under North Carolina law for the standards that govern compounding or any practice of pharmacy for that matter when it concerns human patients versus veterinary patients, so, we enforce the same standards, same oversight, same quality controls.

A bit on the thin edge of the -- thin part of the limb here, I think that there may individual states, whether by statute or by court decision, there have been rulings that a Board of Pharmacy does not have the statutory authority to regulate veterinary products. That is not the case in North Carolina.

Moreover, we're fortunate in North Carolina, at North Carolina State University, and I can't believe as a loyal Tar Heel I'm about to say something nice about NC State, but NC State has a world class veterinary school. And, in fact, the head pharmacist there, Gigi Davidson, is a friend and a constant source of expert advice. So, we have been fortunate not only in our general regulatory efforts to be able to reach out to Gigi for specific advice, both technical and watchdog with respect to veterinary practitioners, whether compounders or non-compounders.

And, in fact, Gigi -- we have a Pharmacy Compounding Working Group in North Carolina that is doing the same sort of very deep dive review of how we regulate compounding, and Gigi is a member of that group, so, we are including the veterinary perspective in everything we do.

DR. WIBERG: If I could just add

really quickly, I'd echo what my two colleagues said. There's no difference in Minnesota under our -- concerning the standards for compounding. All compounding, true compounding, the way we define it, has to be done by either USP 795 or 797 standards as relevant to the product that's being compounded whether it's for animals or humans.

MODERATOR MARCHAND: Dr. Hamburg.

COMMISSIONER HAMBURG: Just a quick question because I know we can easily get behind schedule badly. But I was interested, Jay, in your comment about how there is good data sharing about pharmacists through NABP, but that an equivalent doesn't exist for pharmacies. And I was wondering, and it may actually be a question more appropriate to our representative from the National Association of Boards of Pharmacy, but is there any common database about the sort of universe of pharmacies and what kinds

of things they're doing out there? Because that's, of course, one of our challenges that with the current regulatory schema, we don't know who's out there doing what, unless we hear about it through a problem often.

MR. CAMPBELL: And let me just clarify, you're asking specifically with respect -- about database with disciplinary actions against pharmacists, or pharmacies, I'm sorry.

COMMISSIONER HAMBURG: You raised it in that context, but it made me think is there any kind of shared database for the nation that --

MR. CAMPBELL: Yes. The answer to that is yes, and all Boards of Pharmacy are required to report any disciplinary action we take against any licensee, permittee or registrant to something called the National Practitioner Database, which is a federal database. So, if you guys don't have access to that, I don't know why not, but --

COMMISSIONER HAMBURG: But I meant a compilation of pharmacies, not necessarily related to problems but just in terms of what they are --

MR. CAMPBELL: Oh, a uniform national list of here's every pharmacy in the United States, and what -- no, I'm not aware of that.

COMMISSIONER HAMBURG: I mean, you don't submit to any --

MR. CAMPBELL: I'm not aware that that exists anywhere.

COMMISSIONER HAMBURG: That's why I'm saying, it -- I mean, that might have some utility in mapping the universe, but it might also be highly complex. I just wondered if --

MR. CAMPBELL: I'll reserve judgment on that.

COMMISSIONER HAMBURG: It made me think, you know, does such a thing exist already, because we are struggling with not

even knowing how many pharmacies are out there that might fit into different categories in terms of their practices.

MR. CAMPBELL: Well, and Dr. Hamburg, that -- obviously, each of us here, each of us from a Board of Pharmacy have been responding to a number of information requests for Congressional Committees that are looking into -- and we all -- of course, each state, we have databases of who our licensees, who our permittees are, and to greater and lesser granularity depending on what the particular database is, what their specific practices are. So, I think on a state by state basis, you can get a very good indicator of who the -- certainly, who the pharmacies are with greater or lesser specificity, depending on the particular database of what those pharmacies do. But it raises the same issue that's been at the forefront today, is well, how do you define that? It's easy -- for example, the House

Energy and Commerce Committee to say how many compounding pharmacies exist in your state? Well, at some level the answer to that question is every pharmacy in the state is a compounding pharmacy because every pharmacy will engage in some level of compounding. I think the issue becomes if we are looking at defining some sort of specialty or whatever it is, depending on what that definition is, the databases are easily refined to capture that data. And I'm quite certain that going forward, depending on what happens with federal efforts, or even at the state level in terms of redefinition or specific definition of categories of pharmacy, I think you're going to see more granularity in those databases immediately.

DR. WIBERG: If I could add one thing, as well. Part of NABP's action plan that it developed to address this issue involves extending a license transfer process that we now have for pharmacists. So, Jay's

talking about the disciplinary database and having that information.

Currently, if a pharmacist wants to transfer their license to another state, they go through NABP. And NABP does some background checks, and sends information on to the State Boards of Pharmacy, and then we make decisions about whether or not the person should be licensed.

Well, NABP is talking now about extending that to pharmacies, as well. And you would have to ask Carmen Catizone, the NABP representative about the details. I think this may still be being fleshed out, but how I would envision that working, if it works the way it does for pharmacists, is if a pharmacy in North Carolina wanted to be licensed in Minnesota, they would apply through NABP, provide them with information, NABP will be keeping information on any adverse reactions that states have taken against pharmacies. They'll look at, and then

they'll provide information to me, as the Executive Director for Minnesota about this pharmacy in North Carolina so we can make a more informed decision as to whether or not we ought to license them.

I think if we get to that point, we would be moving closer to having some -- potentially, some sort of a national database. However, it may still not include all pharmacies because not all pharmacies in the state are going to want to ship into another state, so they may never go through this license reciprocity process.

MR. CAMPBELL: Part of the conversation we've had is that business permits are not necessarily ongoing and living. They come and they go, but many states have specific regulations, I believe all of us do, that someone is responsible for what happens in that facility. So, going into the professional who is responsible when the breakdown happened, many boards take action

individually on the pharmacist because if they have been responsible for something that has happened inappropriately, then that action is reported to the national database, and would be there ongoing. Wherever their career takes them, that is part of their licensure history, so in many it's potentially a better approach to be sure that it is in the system because you don't want that person to have the same thing happen at the next facility, where the facility just simply goes away, something else similar rises from the ashes and has a new name.

MODERATOR MARCHAND: Thank you very much. Are there any other points from the FDA panel? If not, I think to keep on our schedule we'll move to our second discussion topic. It's what should the federal role be in regulating higher-risk pharmacy compounding, such as compounding high volumes of drugs for interstate distribution? And the state representatives are on the other side

of the FDA panel, and we'd like to begin with Central Region II. If you'd introduce yourself and tell us your affiliation.

DR. YI: Good afternoon, everybody. My name is Asa Yi. I'm a pharmacist with the New Jersey Department of Health. I just want to summarize our discussion group findings on Discussion Topic 2.

In order to answer this question effectively, we felt that really we need definitions of what compounding is, what manufacturing is, and what repackaging is because there's a lot of gray area without those definitions, and hopefully the definitions will clarify and will bring to light the gray area.

As far as compounding not pursuant to a prescription, we felt that if it's not pursuant to a prescription that it should be considered manufacturing. And if it is considered manufacturing then there should

be federal oversight with federal regulations, and some sort of standard that the states could go by, unless it narrowly meets a federally defined allowance for office use, and an example of that would be nuclear pharmacies preparing diagnostic agents.

With regards to anticipatory compounding, we found there is variability amongst the states. Some states allowed it, some states didn't. The regulations and statutes for different states were different, so we felt that again if it's dispensed without a prescription, then it has to be manufacturing with federal oversight. Thank you.

MR. MOKHIBER: Good afternoon. I'm Lawrence Mokhiber, and I'm the Executive Secretary of the New York State Board of Pharmacy. I want to echo my comments and thanks to the FDA for pulling this group together. I have rarely experienced such a

commitment, such energy, such compassion, and such dedication that I saw in our working group this morning, and it was really fun to be there and to participate in.

I think a couple of points. You know, the Boards of Pharmacy exist to protect the public, and that's to make sure that the drugs are safe and effective. But it also is to make sure that patients have access to them, so a lot of our conversation talked about the whole issue of drug shortages, and what we can do to fix the system for a 21st century solution, and not try to apply unnecessarily 19th and 20th century concepts. So, I think we're all committed to finding new definitions. You're going to hear certain themes for every question and every response, and definition is one of those constant themes.

I also agree and was appreciative of the comments of the Commissioner on the importance of not confusing the public and

what is traditional compounding, which often is sterile or non-sterile, and serves the needs of patients for specific drugs at specific times, and specific formulations. And that is part of the rich history and tradition of pharmacy, and I think it will continue.

Our group looked very carefully at these issues, and trying to answer the question, and the short answer is there is a federal role in the regulation of these entities, but the role varies with the definition. And part of the definitions we also felt needed to be had is the definition of low risk, and high risk, and not necessarily with volume, but those are factors. Certainly, interstate commerce is part one of the definitions that we'll have to look at.

We also focused, as you'll hear time and time again regardless of which group or which question, is the need for better

communication from all of us. And as our colleagues made sure I would say, it's bidirectional communication. We need to make sure we communicate to the FDA, and the FDA to us, and then amongst ourselves. And I appreciate my colleagues' conversation earlier on NABP. NABP is an exceptional informational tool between and among the Boards of Pharmacy.

We also talked significantly about training and education of staff at the state level, FDA support, joint inspections, joint commissioning so that -- I happen to be a Commissioner with the FDA. We want to make sure that that commissioning process continues to be quick and agile, and effective so that we can share information in a timely fashion. If there is an untoward finding somewhere, states individually need to hear about it as quickly as possible, especially if those firms are located in our jurisdiction. We talked about perhaps two-day

training sessions, intense training sessions for patient, excuse me, for personnel who will be engaged in a specialty area of compounding sterile products. And we talked also about the whole issue of what is -- defining what is a manufacturer. Some of the confusion that exists in the public and within the profession, as well, and with physicians and other health practitioners is what is a manufacturer, what constitutes being a manufacturer? Some firms, small, large, good, bad, doesn't matter have been running around saying we're FDA registered manufacturers, and the implication of that is not always known, so we've suggested that that is a -- perhaps, at least from our perspective, one of the low hanging fruits that could be addressed in the short term. Thank you.

MR. JOHNSTON: Mark Johnston, Executive Director of the Idaho Board of Pharmacy. Before I answer this question, I

can't help myself but to weigh in on some of the questions of the FDA panel just briefly.

My colleagues explained that there is no difference in the law between pharmacy compounding of a veterinarian or human use product. However, Boards of Pharmacy rarely, if ever, have reach into a veterinarian's office for veterinarian compounding, or for that matter physician or practitioner compounding which is by and large an unregulated field.

I also wanted to mention that as far as national databases, that NABP is embarking upon an inspection of all sterile compounding pharmacies that are distributing across state lines under the authorization of the Iowa Board of Pharmacy. It's a project that's expected to be completed by the spring of 2013, and all information will be loaded into a national database for everyone to use.

Now, I'll move on to answering the question at hand. The federal

government's role should be to establish a federal definition of manufacturing that withstands judicial review. That last part is important. And the federal government should regulate manufacturing, including shortages, and the state should regulate compounding.

While our group was not entirely comfortable with the term "non-traditional compounding," defining the exceptions to the definitions of compounding or manufacturing, in essence, will be the definition of non-traditional compounding. And these exceptions may address topics such as compounding for office use, dispensing across state lines, not distribution across state lines, which is clearly manufacturing, quantity limits, sterile repackaging, high-risk sterile compounding, and the compounding of anticipatory quantities. These defined exceptions will determine federal, state, or shared enforcement.

MODERATOR MARCHAND: Thank you.

With that, I'll open to the FDA panel to ask questions or clarify points.

MR. BECKERMAN: So, I think we're hearing loud and clear that the definitions are incredibly important, and clarity is incredibly important, clarity of role, clarity of what terms mean. But it strikes me that there is a tension between clarity and some of the issues that you all raised in terms of defining exceptions, whether you call it non-traditional compounding or some sort of special manufacturing. I don't really care about the terminology, but if you want to put in multiple factors, things like anticipatory quantities, whether a product is high risk, whether it's dispensed across state lines, whether it's for office use, at some level all of those factors seem to weigh against sort of bright line clarity in the statute. And I'm wondering if you could address any ideas you might have for how to achieve both clarity and nuance, because

nuance is called for here. After all, a number of these products we're hearing from hospitals are commonly used and are widely used, and are necessary for procedures, heart procedures, cardioplegia solutions, and we don't want to do anything to get in the way of production of those products. So, I think there's a tension between clarity and nuance, and if we draw bright lines you may have people falling on one side of the line that could have adverse effects on the health system, and I wanted to see if you could address that.

MR. JOHNSTON: Our facilitator kept pushing our group to define the exceptions. That's a very difficult task. That is, I think, the most important task at hand. While I don't have an exact answer, and while I'm not speaking for the group as a whole because there was some disagreement, I believe that there's too much focus on compounding, and there should be more of a

focus on what happens to the compounded product. Is it dispensed pursuant to a patient-specific prescription, or is it distributed in the absence of a patient-specific prescription?

Personally, I'm not as concerned with volume, with anticipatory quantities based on history of real life prescription drug orders. I'm more concerned with distribution versus dispensing. And if we limit the conversation to that, I think it does become easier to identify the exceptions.

MODERATOR MARCHAND: Others? Yes.

DR. KIRTLEY: I think, and this is a conversation that many of us have had, it's something where when you start trying to figure out what the specific exceptions are, it's very difficult. That's why you have several people in this room that are talking about you should have a standard on how it is prepared. I don't care if it's prepared for

one person or a thousand people, or you will have this many orders or that many orders, you know, whatever the product is, we need a standard for how it is safely prepared, how you know that it is something that is labeled accurately, that it is sterile, that it is pyrogen-free, it's of labeled potency, and then whatever happens with the product, if the product is safe, then your problems of everything else happen on down the line. So, I think that's whether you're talking about 795, 797, federal oversight on it, states coming to a common minimal standard, whatever that is.

MR. CAMPBELL: I just wanted to applaud you for asking that question, because I do think -- that is the very essence of regulation. Right? As regulators in the public, we think surely there are these bright lines, and it's certainly easy to stand at a distance and ask why can't there be a bright line. And as you brought -- there

is a lot of nuance here. And that nuance ties into patient access. And I think -- I hope that we won't get too bogged down, as I mentioned in our group, let's not let the perfect get in the way of the good. We're not going to be able to make a distinction that is razor sharp, but I think in the main, the cases that concern us aren't the cases in that gray area.

I think no rational person would argue that the activities that NECC engaged in, it was a close call as to whether that was compounding or manufacturing. It's clearly manufacturing under any definition you choose. And I think one of the things we have to recognize that there are going to be the gray areas in the middle no matter how well we write a definition. And I think as we'll discuss on some of the subsequent questions here, I think information sharing and partnering between our state and federal level regulators are going to help us sort

through the harder cases on a case by case basis. That's often not satisfying to people generally and to pharmacists specifically, but I do think inevitably that's got to be a huge part of what we do.

MODERATOR MARCHAND: Mr. Mokhiber.

MR. MOKHIBER: Yes, I was just going to add that I think it's a fair question, but I think the nuances are going to have to be addressed. For our listeners who are not pharmacists, many of us use the term "high-risk" to talk about trying to make an end product that is sterile, having started with non-sterile chemicals, perhaps properly assayed, perhaps not. That, in my mind as a pharmacist, is significantly different than taking a commercially available sterile product and in a very good, and secure, and sterile environment reducing that to smaller package sizes which, you know, if often the case, and is often the demand we see from our hospitals and other

institutions. So, yes, I don't want to put too many layers before we get to the bright line either, but I think we have to somehow separate, or at least include those in the discussion before we make a final decision.

MODERATOR MARCHAND: Yes, Bernadette.

DR. DUNHAM: Just a quick question, and that is when you mentioned a minute ago labeling, so --

MODERATOR MARCHAND: Could you just speak a little bit louder into the microphone?

DR. DUNHAM: What is the comfort level of actually saying this particular product is compounded and putting that on the label? Do you have any views on that?

MR. MOKHIBER: What is the comfort level for what?

DR. DUNHAM: If you actually put on the label of the compounded product that it was compounded?

MR. MOKHIBER: As a pharmacist, if we were to put that on, that might mean something to other pharmacists and maybe to the physicians who buy it. Would it mean much to the patient who knows they need surgery today and without it, you know, I'm not sure. I think it's more incumbent upon us to put the standards in place and then collectively, the boards and the FDA, enforcing those standards as opposed to labeling, which most people won't really know the subtle distinction, in my opinion. Maybe it's not so subtle, but I don't think most patients will get it. That's my personal opinion.

MODERATOR MARCHAND: Mr. Kirtley.

DR. KIRTLEY: I was just going to say, I don't believe that most of our pharmacies have any problem putting on that it is compounded. We have pharmacies that have some sort of hybrid registration with FDA and put it on the FDA website even that this is not an approved drug. It is a

compounded drug. So, if you look at the number on the package it has the name of a pharmacy and it links even on a federal website that it is a compounded product. So, we require that if you're compounding something that's for office use, if it's outsourcing for a hospital, that that product cannot be resold. It is either directly to a patient, or to a prescriber or a hospital to be administered in that facility. So, I don't believe we have a problem with telling people it's compounded.

MODERATOR MARCHAND: Jane Axelrad.

MS. AXELRAD: Yes, I wanted to follow up on the issue of repackaging, which clearly is a large category of activity that's conducted by compounding pharmacies. And I wanted to know how you would feel if we were to simply say repackaging is repackaging, and we don't consider it compounding. And then decide how repackaging would be regulated separate from how we

regulate compounding.

MODERATOR MARCHAND: Dr. Hamburg, since you --

(Off microphone comment.)

MODERATOR MARCHAND: Okay.

MR. MOKHIBER: By all means, if you'd prefer. I can't respond for the group completely, although it did come up in our discussion that perhaps that is part of the way out of the dilemma we find ourselves, is to -- just as there are repackaging provisions in the Food, Drug & Cosmetic Act for solid dosage forms, that perhaps there is a middle ground of repackaging for sterile, compounded sterile, or manufactured sterile products into smaller units of use that is distinguishable from other forms of compounding. And perhaps that is an issue to be considered.

I think in our group that was an issue that was given some consideration. I can't tell you that we reached consensus, or

that anybody was ready to say that was the -- we found the Holy Grail, but I think it was certainly one of our considerations.

DR. YI: I would also just caution you with that because if you're talking about repackaging oral dosage forms, the risk is a lot lower than repackaging a sterile injectable product from a larger vial into let's say smaller units, smaller vials, or predrawn syringes, something like that. The risk is higher and greater patient harm could come out of it.

MODERATOR MARCHAND: Dr. Bernstein.

DR. BERNSTEIN: Thank you. Just to follow-up on Jane's question and some of the issues related to high risk. So, if a facility is doing high-risk and low-risk repackaging, packaging for -- with prescription, can it or should it be both a pharmacy and a manufacturer? Did any of you talk about that in your discussions? And I

say that only because the question -- someone mentioned over here that we need some clarity over what's the state's role, what's the FDA's role, and what's a shared responsibility. And I think we're all talking here that what we really need is greater clarity across the board. And when you get into something that could be both then you're getting more into this kind of gray zone where you lack that clarity. So, can there be such a thing?

MODERATOR MARCHAND: Mr. Johnston?

MR. JOHNSTON: We did speak to dual registration like that and the fact that it clouds even more. If it's the same facility registered under two different standards, which standards do you enforce? And the group's general consensus was if there's going to be two different licenses there should be two distinct different facilities, while maybe under one roof, two different separate facilities because it

would be impossible to know which set of standards to enforce in what situation.

DR. KIRTLEY: I can speak specifically for some pharmacies in Arkansas, not for the Southwestern group, but --

MODERATOR MARCHAND: Mr. Kirtley, thank you. Okay.

DR. KIRTLEY: I'm sorry.

MODERATOR MARCHAND: I just want to make sure that everybody on the webcast knows who's speaking.

DR. KIRTLEY: Okay. I figured I have a fairly distinctive voice. We have pharmacies that they would be I think very open, and have even pursued having some sort of hybrid registration or designation even if it's as an outsourcing pharmacy, just like a repacker would do, because they feel as if they are trying to meet a higher standard than what we might just have as a Board of Pharmacy. And to be able to show if they're crossing state lines, this is where we get

into the federal-state interaction that there is a higher standard for whether it's beyond use dating, taking non-sterile to sterile, or whatever it is, that they are willing to meet and have oversight from both the state and the federal government to come in and say if you see something that we need to improve, let us know what it is. We want to fix it, because we don't want to have those problems, but we see this need in an area, and we want to be able to safely prepare medications for these patients.

MODERATOR MARCHAND: Thank you. Any other -- Dr. Hamburg.

COMMISSIONER HAMBURG: I just wanted to propose really that I think this issue about defining the terms, compounder, manufacturer, and how that then aligns with regulatory responsibilities and actions is just so, so fundamental and I think we've surfaced a lot of the issues and concerns, but I think we ought to have a -- I know we

have some working groups now, but we ought to really continue this discussion with some of the people represented here with ASTHO and NABP, and really try to see if we can come up with something that really gets more to the tension as described between clarity and nuance. Because I think that the ramifications of not getting it right, or at least not getting closer to what's right and being explicit in a definitional way does put a lot of things at jeopardy. As Cody, I think, indicated there are a lot of sub-issues and we need to make sure that the decisions we make, the approaches that we pursue, and potentially what might go into new legislation really reflects all of the different perspectives and experiences. So, I just think this is so important that we need to really, not now because I know you're mindful of time, but continue this discussion and really move towards some broader clarification and definitions.

MODERATOR MARCHAND: Thank you. All right. With that, I think we'll move on to the Discussion Topic 3, and it is, is there a way to rebalance federal and start participation in the regulation of pharmacy compounding that would better protect public health? What strategies should be developed to further strengthen federal and state communications? And we'll begin back on this side of the table closest to me, and Mr. John Kirtley from Arkansas.

DR. KIRTLEY: Thank you. I'm glad that this is hopefully a quicker flow through so we try to get out side of the table to speed things along.

I think this is something, and this is not a statement to denigrate either the Boards of Pharmacy, Departments of Health, the FDA, or anyone else, but I think that we all recognize there are opportunities for improvement here. There are definitely some opportunities for us to increase

communication whether that be between states, or between states and FDA by the state and federal regulators.

With that, some suggestions that we would have is to increase and improve the FDA outreach to everyone, so not only just us as state regulators, but also directly to hospitals, state agencies, industries, outsourcing pharmacies, ad mixture, traditional, non-traditional, whatever jargon you want to put in there, that when we do that, and even potentially picking up some things such as regional meetings. We have some states right now that we're planning on having a regional meeting, sit down to show amongst each other and invite FDA in to say here's what we do when we go into one of these pharmacies. Here are the inspection forms we use, this is the training we've had for our staff, so give us feedback. Here's what we've got, shoot holes in it and tell us what we're missing. Also, what can we do

together to improve the searchability for information on our websites, and even with the FDA website so that if you are trying to find something there's a little bit easier search tool, or there's a little bit easier access to determine directly where it is. I know with our own websites sometimes you say okay, get on the website, click in the top left corner here, and then you drop down four rows, on the third page on the right-hand, you guys get the point. It's difficult to find information.

With that, you could also say that you could provide resources to the states to give oversight of pharmacy compounding or specific training to our staffs. Although many of us have professional staffs that are pharmacists with years of experience, or years of experience doing surveys, it's what exactly would you look for?

I've never been given the

opportunity necessarily to see how the FDA would inspect a CGMP facility, or how you would look at a manufacturer, so there are things I could pick up there that my staff and I could use when we go into these pharmacies.

Creating a centralized systematic method of sharing inspection data from FDA with the states, and I think conversely from the states back to the FDA. We all have different Freedom of Information rules. Some of us, our inspections are wide open. If you want to see what happened with the pharmacy inspection in my states, it's something that you ask, you've got it. I can show you years of past data of what we've done. Some states are not able to release that, and in instances of cases, the FDA is not able to release that to the states. So, it's something we can all work on.

The last couple of things is we often see where either a state or the FDA has

an issue with a pharmacy. So, whenever we have a case, a warning letter or something, usually that elicits a response from the pharmacy. And, yet, what we might not have is a close to that loop. We don't know that there's a warning letter, there's a response from whoever got the warning letter, so then what happens? What's the wrap-up? Is the response sufficient or are there other items that need to be fixed? And it's something that I think that the FDA needs, and the states need, as well as whoever the permit holder is that's responsible for it.

MODERATOR MARCHAND: Mr. Campbell.

MR. CAMPBELL: Thank you. Jay Campbell from North Carolina. These are my perfect categories, but I'm going to focus on communication, as well, because I think the first question here about rebalancing is sort of the whole point of the discussion of every one of these. So, let me focus on communication.

First, general information availability. I agree, any FDA action, whether it's a warning letter or other action that needs to be reported to NABP so that it goes into the building database of pharmacy actions, and it needs to go at a minimum to the home State Board of Pharmacy.

I think that that communication directly to the state regulators has been sporadic, at best. And, certainly, even it goes to one state, it's not necessarily going to others.

I do think that the FDA's website contains all manner of terrific information. Finding it sometimes is more than a bit of a challenge, and I think that, again, to use your phrase, Dr. Hamburg, I think some low hanging fruit there is providing specific consolidation of information directly relevant to state regulators onto an easy to access page or portal would go a long way at very low cost.

Also, second sort of category I talk about would be specific information sharing. Understanding that there are probably federal law barriers that you have to deal with, my experience is that in getting sharing of information specific to an investigation that FDA is conducting is ponderous, at best. Ponderous in terms of opening up the avenue for sharing that information, and often not timely in the reporting of that information to the states. If two years pass between the opening of an investigation and some sort of FDA resolution, and the states are sort of waiting to figure that -- that's too long. And I think everybody would agree with that.

We've already mentioned -- you mentioned, Dr. Hamburg, at the beginning this is a historic meeting, and you're right, and it shouldn't be. These meetings at the national level between state and federal regulators, as well as at the regional and

local level -- I'm not saying we -- we're all overburdened people, so we don't need to fill up our calendars with meetings just for the sake of having them. But I think even for -- and maybe especially at the local, the individual state level, having regular communications with our FDA liaisons and others, it may not be about a specific case, but it helps build a relationship. And the more that we have these relationships, and the more we have a level of trust in each other, hopefully trust in each other. I hope it doesn't result in less trust, but I think we have more trust, then a lot of these information sharing things take care of themselves and don't necessarily have to be formal mechanisms.

And then, finally, what I describe as a raw category, information gathering. All of this stuff has to be a two-way street. If you gather information that we need, you need to share it with us. If we

gather information that you need, we need to share it with you. Let's make sure that it is a two-way street.

Board regulators can very much be an -- board investigators can very much be, I think, a good tool for the FDA in terms of going in with you on inspections, or helping you investigate a particular problem. We need to look -- whether that's credentialing, or commissioning, or whether it's a less formal thing, we need to have easier paths to walk into a facility that we're concerned about, because it goes back to the question asked before, can we have perfect clarity? We can't. We can do better, perhaps, but we can't have -- I think Justice O'Connor once wrote in an opinion that folks often come up with grand unified theories of the law that are neither grand or unified, and I think that applies here. But if we can have opportunities to go in together, we may find the clarity we need, not necessarily in the

regulatory definition, but in the facts we find on the ground, and the ability to go in and do those things together, again, whether it's credentialing, or whether it's Memoranda of Understanding, or whatever it is, I think those things would very much improve the job that you do as federal regulators, and the job that we do as state regulators.

John was spot on the mark there. We have very often had our investigators go in with DEA agents, or had DEA agents come in with us. And if you can get rid of that territoriality aspect, we're going to be in here and you're not, we found that sort of educational working process to provide tremendous regulatory benefits. So, those would be our suggestions about communications and working together. And I do think that's low hanging fruit.

MODERATOR MARCHAND: Thank you. Mr. Wiberg.

DR. WIBERG: First, I'd echo what

Jay said. Our regional group when we addressed this topic question really didn't spend a whole lot of time on the rebalancing federal and state participation because really if you take a look at Topics 2, 3, and 4 together, it's really about what are the -- what is the state role, what's the federal role? How can they be rebalanced? So, we did spend a lot more time talking about communications.

I'm actually going to be pretty brief because my colleagues here have already talked about almost all of the things that we've talked about, so there must be some commonality between the regions.

There was one thing, I can't remember if they added it or not, just looking through this list as they were talking, and that's webinar training. If there's any sort of webinar training that the FDA could provide to states, state regulatory agencies in those areas where there is common

regulatory concern that might be appreciated.

And I can say that in Minnesota we've been actually pretty happy with our relations with the local FDA office. We actually work with them quite a lot. In fact, in between sessions when I was checking my email, one of the staff at the FDA office in Minneapolis said -- answered a question that one of our -- that our chief surveyor had about issues, so I think we communicate well. I think there's always room to do even more, and there probably definitely is -- as we go forward here, I think there's going to be the need if both the FDA and the states have resources to do joint inspections and investigations of some of these facilities.

MODERATOR MARCHAND: Okay, thank you. With that, I'll open it to the FDA panel for questions, points to clarify?

COMMISSIONER HAMBURG: My sense is we all agree that there's some real opportunities here to strengthen our day to

day activities and our crisis response activities, and it will benefit us all. And some of it we should start on, you know, tomorrow.

MR. CAMPBELL: And I would single out, we have a specific FDA state liaison named Brett Weed. If Brett's watching, hi, Brett. And it's been a very good star. And it's nice to have that contact person, and he's available and easy to reach. And that's good. Even better is getting the information back, so let's make sure we all -- we'd all be happy to be in touch with each other and that's important, but I think we've got to make sure that we're not just in touch, we're actually passing information back and forth.

COMMISSIONER HAMBURG: And I guess I should underscore -- I'm sorry, Howard, but I believe it was our colleague from New York who underscored bidirectional. And bidirectional really matters, and I think the back and forth flow is key, and you've

spelled out very well some ways in which we can clarify how we present information, but also getting that feedback from you, and information about what you're finding or what concerns are is really important to us, because that may actually trigger an action where we didn't know there was a problem, because we don't have other mechanisms sometimes for getting access to information in this compounding pharmacy area, or we don't have the on the ground responsibility for oversight and regulation. So, that would be terrific. And, of course, our regional offices provide one way, but hopefully we'll have some additional mechanisms that will be clarified to help with that, and we're eager to work with you on some of the training, and education, and shared inspectional activities that you described, as well.

MR. SKLAMBERG: And we found on the food side where the cooperation is imperative, and indeed is required by the

Food Safety Modernization Act, that really there are kind of two levels of the contact. Some are in more formal settings like this, and conferences and through training, and probably even more importantly is the day to day interactions that then flow from that through, as Dr. Hamburg pointed out, our district offices. And that those contacts hopefully over time become more and more routine, that it literally is, you know, a cooperative venture in terms of how we deal with this problem.

MODERATOR MARCHAND: Okay.

DR. DUNHAM: Bernadette Dunham, just a quick follow-up. I couldn't agree more. I think it's one house, and I think everybody right now wants to see everybody working together. It's bringing the best out of the states, and the federal government to address these issues because it impacts public health. And the more that we figure out how we're able to share information, and

many times I know, I'm not a lawyer, that brings in the legal of how do we do this. But if we all want to make a success story sitting down with your wonderful recommendations that you've shared with us, we can make it happen. And that's why I think this particular meeting is so significant, so I can't agree with you more. Thank you.

MODERATOR MARCHAND: Okay, thank you. Well, let's move on to our fourth discussion topic. Do you see a role for the states in enforcing the federal standard for non-traditional compounding? If so, what role? What factors would affect a decision by your state to take on such responsibility? And let's move to the other side of the table and begin with Central Region I. I'm sorry, Central Region II. Mr. Yi.

DR. YI: Thank you. Yes, our group definitely felt that there was a role for the states to play based on federal standards that would come out of this. This is

dependent on resources from state to state. A lot of the resources that the different states in our group that participated in the discussion, the resources differed from state to state, so that's a big factor.

One resource was manpower and funding. And the -- I guess the ideas that came up was maybe it could be modeled after the CMS program for surveyors of health care facilities, nursing homes, ambulatory surgery centers, hospitals, where CMS funds the surveyors in each state to do the inspections on behalf of CMS. So, if we could maybe look at that model and take some parts out, that would be beneficial.

Also, joint state and federal FDA inspections, as was discussed earlier. Training is a big thing, also, that came up time and time after again, training so that all 50 states are on the same page of what to look for when they go out and do these inspections. And training on just things like

USP 797 and just if there's revisions to accepted standards of practice, again training on those so everybody's on the same page.

Also, communication. This is another topic that's come up time and time again today, just communication between the states and between FDA and the states. That would be helpful.

MODERATOR MARCHAND: Thank you. Mr. Mokhiber.

MR. MOKHIBER: Thank you. In the interest of time, it's been a long day and I'm really tempted to just say ditto. But we said the answer is yes, it was an affirmative from all of our participants in our work group, but the degree of yes, again follows the definition. And just as we enforce other provisions or underwrite and reinforce other provisions of federal law, controlled substance law, the consumer products safety laws on child-resistant containers, sure,

there's a role for the states. And it would be greater or lesser about how we ultimately define this third category, if you will, or the establishment that we're really talking about. So, the answer, the short answer is yes. And then fill in the blanks as we fix the definitions.

Everybody thought it was critical to make sure that whether or not pharmacists were involved in the process, so if we were to take an establishment where there wasn't a pharmacist in charge, or supervising pharmacist, or responsible pharmacist for the production of the product as there may not be in certain manufacturing plants, our role would be diminished. We perceive that probably what would come out would be some hybrid where pharmacists will be involved, and our involvement will stay at a higher level.

We would also look at, you know, some of our colleagues who were impacted most

directly by the NECC mess. Again, this has to be now, not sometime in the distant future. Funding and training were important. We also looked at the CMS model of perhaps cost sharing for the states who would do some of the work to help to make sure that federal provisions are met. And, again, I want to thank you.

MODERATOR MARCHAND: Thank you. Mr. Johnston.

MR. JOHNSTON: I think this question is a little more tricky. I'm certainly not an attorney, but this really comes down to a basic of law. States can only enforce which they have statutory authority to enforce. Many states, I'd say most states can't carte blanche enforce federal law, so do you see a role for the states in enforcing a federal standard of non-traditional compounding? Really the short answer is no, we can't enforce federal law. However, if the federal government was to define

manufacturing, what's left over is compounding, and compounding the states can enforce.

Also, the FDA could engage in training of state inspectors and through a commission process the FDA could contract with a willing state to perform inspections to the federal level. That's entirely possible.

Also, states could incorporate by reference the federal law, but that's yet again another step which takes some time, so on its basis, I think the answer is no. However, I think there's plenty of room to work on that.

MODERATOR MARCHAND: Thank you. All right, FDA panel, Howard Sklamberg.

MR. SKLAMBERG: Yes. I think part of this is kind of in a play in the word "enforce." I mean, if we're talking about going in and inspecting and evaluating against a federal standard, when it comes to

actually enforcement as in say going to court, that might be the federal responsibility. And I guess the word "enforce," there are different definitions. There is surveilling and inspecting, and then enforcing, and it depends how a law would be written, and how that -- how those responsibilities could be distributed.

COMMISSIONER HAMBURG: I think we heard from some of your colleagues earlier today that there are clearly programs where there are federal standards and states are inspecting to them working with the relevant federal agency. I mean, you just mentioned the CMS surveys which is sort of a variation on that theme in some way, and within FDA those of you from State Health Departments are probably familiar with our mammography quality inspectional activities where we have a program that gives grants to -- I'm not a lawyer. I'm not sure what form they're in so I won't say that, but resources to states in

order to be part of this program which is inspecting to a set of uniform national standards. So, I think that there's a way to frame it and I think, you know, it would -- this question sort of depends on our being able to come together and really figure out what we mean by non-traditional compounding, and probably requires that there be some legislative action, as well, to create new programs in this arena. And, you know, there are probably resource questions that will become salient here, as well. But I think it's the concept of that enhanced partnership in this arena that I think we were trying to get at, and my sense is that there the answer is yes, that we do see a role, whether it's in communication, or training, or development of clearer standards that the working together is important. But that this last question, you know, does depend not just on the semantics and interpretation of how we phrase the question, but also on some broader

contextual issues that will be ongoing. But I think it's something we can continue to drill down on as we work either through the sort of working group that I proposed earlier when we were discussing I think Topic 2, or other existing mechanisms.

MODERATOR MARCHAND: Mr. Wiberg, comment?

DR. WIBERG: Yes. I would just say that I actually do think it's possible for states to enforce federal standards. There are ways that it can be done. In Minnesota there's a couple of different things.

In the statutes created by the legislature, the enabling statute that creates the Board of Pharmacy, in the Powers and Duties section it says, "It shall be the power and duty of the Board of Pharmacy to," and one of the things it talks about, and it's not the exact language, but to regulate the quality and purity of drugs in accordance with relevant federal standards including

those set by the United States Pharmacopeia, et cetera. So, if there were a federal standard established either in statute or by the FDA as a result of statute, I think that we could amend our state statutes to reflect that we also need to enforce that standard.

The other thing is the Board of Pharmacy in Minnesota, and probably most states, derives its real authority to do something -- well, our real authority to do something is based on the fact that we issue licenses. And we can take licenses away as part of a disciplinary process. And the Board has adopted by rule a definition of unprofessional conduct. And unprofessional conduct in Minnesota includes failure to follow all federal, state, and local statutes, rules and ordinances related to the practice of pharmacy. So, we can actually -- even if we weren't going to court to enjoin some practice, which the FDA might have to do, what we could do is we can go to the

pharmacy and say you're not following these federal standards. That is unprofessional conduct. You need to follow those standards or we're going to potentially take disciplinary action against your license.

I will say that there is one area, and one of the things I emphasized in our group, and why it can be critical in the future for the FDA to do joint investigations with states is with most states, except I guess for the State of Ohio, pharmacy boards are regulatory licensing agencies. We're not law enforcement agencies. We can't initiate criminal proceedings. The FDA can, so that may be in some of these really horrible situations something that's going to get the attention of folks even more than what we can do.

I say the same thing about the DEA. We can go in, we can discipline someone's license, we can't put people in jail, so that is one thing I think the FDA

still would need to be involved.

MODERATOR MARCHAND: Thank you. Any other FDA panel members? No? Well, we've come to the end of the fourth discussion point, and that will be concluding our interactive dialogue with the 50 states, the intergovernmental meeting as well as the public meeting. And I certainly would like to thank the states for their active participation today. It was a very active and dynamic work group sessions that we had earlier in the day, and I certainly would like to thank the state representatives who spoke at the public meeting, so appreciate that.

And, also, I'd like to thank the FDA staff that made this possible, and I'd like to just call out our facilitators who were involved in the working groups, Gail Bormel, Beth Rich, Anna Fine, Connie Jung, Lesley Maloney, and Mary Kremzner. Thank you very much for actively working in the working

groups. And, also, I'd like to point out Colleen O'Malley who is our sort of our facilitator in residence here at the FDA, and was involved in training the group. As well, the note takers, Selena Prasad, Kathy Miller, Stephanie Joseph, Edisa Gozun, Lindsay Davidson, and Brenda Rose. And special thanks go also to Steve Morin who was involved in registering, James Valentine for making sure things went smoothly here in the room today, and Dan Zeppi for making sure the webinar went as it was supposed to. And, again, we had over 500 people on the webinar.

And before we conclude, certainly Pat Kuntze for managing all the logistics with regard to the meeting, and Virginia Cox for making sure that the team was led and brought forward the right group of people to pull it off today.

So, with that, I'd like to also ask the Commissioner to come for some closing remarks. Dr. Hamburg.

COMMISSIONER HAMBURG: Why don't I just speak from here, and you'll be glad to know that I am not going to try to do an overview of all the most interesting and important issues that were raised over the course of the day. Rather, I want to thank you all, you know, really, sincerely that your participating in this meeting has made a real difference to us. We have all learned a lot, and I think together we've been able to identify a set of important near-term and longer term steps. And I think we will be able to put in place some new systems and partnerships that will be really, really important and make an enduring difference.

So, let me just say this has been a rich discussion, but a very long day. Kudos to our moderator for keeping us not only on schedule but actually allowing us to end a little bit early. I know many of you have planes to catch, and I will just close by saying, you know, Happy Holidays to all of

you. Thank you for the good work that you do, and the work of the organizations that you represent. We intend to continue these discussions and to work closely with you, and I wish you all safe travels, and all the best. Happy Holidays.

(Applause.)

(End of webcast.)